product development protocol for the total TMJ prosthesis (21 CFR 872.3940), the glenoid fossa prosthesis (21 CFR 872.3950), the mandibular condyle prosthesis (for permanent reconstruction; 21 CFR 872.3960), and the interarticular disc prosthesis (21 CFR 872.3970) under section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)).

Procedure: On May 10, 1999, from 10:30 a.m. to 5:30 p.m., and May 11, 1999, from 8 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 5, 1999. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 11:45 a.m. on May 10, 1999, and between approximately 8:15 a.m. and 8:45 a.m. on May 11, 1999. Near the end of the committee deliberations on each day, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 5, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On May 10, 1999, from 5:30 p.m. to 6:30 p.m., the meeting will be closed to permit discussion of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding dental device issues.

FDA regrets that it was unable to publish this notice 15 days prior to the May 10 and 11, 1999, Dental Products Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Dental Products Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 20, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–10509 Filed 4–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0972]

Policy on the Disposition of Publications That Constitute Labeling; Draft Revised Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised Compliance Policy Guide (CPG 7153.13) entitled ''Regulatory Policy on the Disposition of Publications that Constitute Labeling.'' We are revising the current CPG to provide clarification and further guidance to our field employees about when publications may constitute labeling for regulated products and to stress our policy with regard to the disposition of these materials when they cause a product to be in violation of the Federal Food, Drug, and Cosmetic Act.

DATES: You may submit written comments on the draft revised CPG by July 26, 1999.

ADDRESSES: You may submit written requests for single copies of the draft revised CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420. Please send two self-addressed adhesive labels to assist us in processing your requests, or you may fax your request to 301–827–0482. Please see the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft revised CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane rm., 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JoAnne C. Marrone, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1242.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has had a longstanding policy related to the seizure of books that constitute labeling for a product. We articulated this policy in a Compliance Policy Guide (CPG 7153.13) in December 1982, which we revised on August 31, 1989. In recent years, questions have arisen concerning when published materials may constitute labeling for regulated products, as well as our position and policy on the disposition of these materials. We intend this draft revised CPG to clarify these issues and to improve guidance to our field employees.

This draft Level 1 guidance document is being issued consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the disposition of publications that constitute labeling for a product that renders a product violative. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Request for Comments

You may submit to the Dockets Management Branch (address above) written comments on the draft revised CPG entitled ''Regulatory Policy on the Disposition of Publications that Constitute Labeling.'' You must submit two copies of any comments, except that you may submit one copy if you are an individual. You must identify your comments with the docket number found in brackets in the heading of this document. The agency will review all comments, but in issuing a final CPG, need not specifically address every comment. We will make changes to the CPG in response to comments, as appropriate. You may see a copy of the draft revised CPG and comments received in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

You also may download copies of the draft revised CPG to a personal computer with access to the World Wide Web (WWW). The Office of Regulatory Affairs' (ORA) home page entitled ''compliance references'' includes this draft revised CPG, and you may access it at ''http//www.fda.gov/ora/compliance_ref/default.htm''.

Dated: April 20, 1999.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 99–10359 Filed 4–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0239]

Draft Guidance on Resolving Scientific Disputes Concerning the Regulation of Medical Devices; Administrative Procedures on Use of the Medical Devices Dispute Resolution Panel; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel.'' Section 404 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) directed FDA to ensure that it has effective processes to resolve the scientific disputes that occasionally arise between FDA and the regulated industry, including a review by an appropriate panel of experts to advise the agency on issues upon which industry and FDA professionals differ. This guidance is neither final nor is it in effect at this time.

DATES: Written comments concerning this guidance must be received by July 26, 1999. Written comments concerning the information collection requirements must be received by June 28, 1999.

ADDRESSES: Written comments concerning this guidance must be submitted to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies on a ''3.5'' diskette of the draft guidance document entitled ''Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the collection of information requirements to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: James G. Norman, Center for Devices and Radiological Health (HFZ–2), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–4690.

SUPPLEMENTARY INFORMATION:

I. Background

FDA provides various mechanisms by which the device industry can obtain reconsideration of FDA decisions and actions under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), the Administrative Procedure Act (5 U.S.C. 551 *et seq.*), and agency regulations. These processes are summarized in a guidance document entitled ''Medical Device Appeals and Complaints Guidance on Dispute Resolutions,'' which is available from the CDRH web site at ''http://www.fda.gov/cdrh/resolvingdisputes''.

Section 404 of FDAMA added to these various mechanisms by directing FDA to ensure it has effective processes by which a medical device ''sponsor, applicant, or manufacturer'' can obtain independent review of a ''scientific controversy'' between that person and FDA. In the **Federal Register** of June 16, 1998 (63 FR 32733 and 32772), FDA published a direct final rule and a companion proposed rule amending § 10.75 (21 CFR 10.75) to add another method of resolving scientific controversies. This amendment stated that sponsors, applicants, or manufacturers of drugs (including human drugs, animal drugs, and human biologics), or devices may request review of scientific controversies by an appropriate scientific advisory panel or advisory committee. (Hereafter in this document, the term advisory committee includes scientific advisory panels.) By this amendment, FDA clarified that sponsors, applicants, and manufacturers of drugs, biologics, and devices are not limited solely to requesting internal supervisory review, but also have the right to request review of scientific controversies by appropriate advisory committees. FDA believes that in appropriate circumstances, advisory committees can provide the agency with useful insight and advice about the resolution of scientific controversies.

FDA initially used the direct final rule because it believed the amendment to § 10.75 was noncontroversial and in accord with FDAMA. In accordance with FDA's procedures for direct final rulemaking, the direct final rule stated that if FDA received no significant adverse comments, the direct final rule would go into effect on October 29, 1998. The direct final rule stated further that if FDA received any significant adverse comments, it would withdraw the direct final rule and consider all comments received on the companion proposed rule in the development of a final rule using the usual notice and comment rulemaking procedures. The comment period for the companion proposed rule ended on August 31, 1998. FDA received significant adverse comments in response to the direct final rule and the companion proposed rule. Therefore, in the **Federal Register** of September 23, 1998 (63 FR 50757), FDA withdrew the direct final rule.

Significant adverse comments asserted that the amendment to § 10.75 failed to provide a procedure that sponsors, applicants, and manufacturers could follow to request reviews under section 404 of FDAMA (section 404 reviews). The comments suggested that the regulation called for by section 404 of FDAMA should contain information such as the process for selecting members of an advisory committee convened to conduct a section 404 review, the timeframes for conducting the reviews, the standards for granting or denying a section 404 review, and the weight to be given to advisory committee recommendations.

In a final rule issued in the **Federal Register** on November 18, 1998 (63 FR 63978), FDA acknowledged the usefulness of much of this kind of information, but concluded that it should not be included in § 10.75. Because of the significant differences among FDA centers in applicable statutory provisions, existing appeal and dispute resolution mechanisms, and approaches to advisory committee management, FDA is adopting a center-based approach to the implementation of section 404 of FDAMA. Each affected center is responsible for developing and administering its own processes for handling requests for section 404 reviews and is issuing a guidance document containing specific information of the type suggested by the comments. The substantive differences in the programs in the affected centers, and the different matters that could be